

REMARKS

The Office Action mailed August 21, 2008 has been received and reviewed. In the Office Action, the Examiner has:

- (1) objected to claims 1 and 63 for certain informalities;
- (2) rejected claims 1, 4, 6-8, 10, 12-13, 17, 20, 27-28, and 63 under 35

U.S.C. § 102(e) as being anticipated by Streeter (U.S. Publication No. 2006/0247492);
and

- (3) rejected claims 1, 4, 6-8, 10, 12-13, 17, 20, 27-28, and 63 under 35

U.S.C. § 103(a) as being unpatentable over Streeter.

In connection with the present Response, claims 1 and 63 have been amended. No new subject matter has been added in connection with the amendments. Upon entry of the amendment, claims 1, 4, 6-8, 10, 12-13, 17, 20, 27-28, and 63 are currently pending in the present application.

In view of the above changes and the following remarks, Applicants respectfully request reconsideration of the claims.

Claim Objections

With respect to item (1), claims 1 and 63 have been amended. In particular, the language "either leaflets" has been amended to "the leaflets."

35 U.S.C. § 102

With respect to item (2), the Examiner has asserted that claims 1, 4, 6-8, 10, 12-13, 17, 20, 27-28, and 63 are anticipated by Streeter.

Independent claims 1 and 63, directed to an implantable device, have been amended to now recite, among other things, *each restraining member being sufficiently situated from an adjacent member, so as to support free margins of any leaflets and to minimize an occurrence of the leaflets from slipping through a space between adjacent restraining members*. Support for this amendment can be found, for example, in paragraphs 55 and 56 of the present application.

In contrast, Streeter fails to teach or disclose a device where each restraining member is sufficiently situated from an adjacent member, so as to support free margins of any leaflets and to minimize an occurrence of the leaflets from slipping through a

space between adjacent restraining members. Streeter is directed to a valve shield that includes a shaped sheet of material adapted to be affixed to the annulus of a valve and adapted to extend over at least a portion of a valve leaflet, so as to assist or replace the closing function of that valve leaflet. Streeter lacks any teaching or disclosure directed to sufficiently spacing one restraining member from an adjacent member in order to minimize slippage or protrusion of the leaflet through the space between adjacent restraining members.

While the Examiner has asserted that the similarity of Streeter device to the present invention would anticipate the present invention, it should be appreciated that the spacing of the restraining members in the Streeter device may not be sufficient to minimize leaflet protrusion through the spacing between adjacent restraining members. If the Examiner may note, in paragraph 56 of the present application, it is provided that the free margin of a leaflet must be supported at least every 5-7 millimeters along the leaflet. Any spacing between adjacent restraining members larger than 5-7 millimeters would, thus, likely result in protrusion of the leaflets through such a spacing. Since the Streeter device and the device of the present invention must be relatively similar in size to cover the leaflet valve, and since the Streeter invention contains only five restraining members, as the Examiner has noted, while the present invention contains six restraining members, the use of only five restraining members across a similarly sized device would result in a space larger than 5-7 millimeters between adjacent members, and would thus not be sufficient to minimize protrusion of the leaflet through such a space.

Moreover, it should be noted that the limitation provided in the amended claims, although may be functional in nature, such functional language does not render a claim improper. As clearly provided in M.P.E.P. § 2173.05(g), “a functional limitation is often used in association with an element, ingredient or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.”

Since Streeter fails to teach restraining members having a design that sufficiently situates each restraining member from the other in such a manner so as to support free margins of any leaflets and to minimize an occurrence of the leaflets from

slipping through a space between adjacent restraining members, Applicants submit that claims 1 and 63, as amended, are not anticipated by Streeter.

Claims 4, 6-8, 10, 12-13, 17, 20, and 27-28 are dependent from claim 1. As such, it follows that these claims are also not anticipated by Streeter.

35 U.S.C. § 103

With respect to item (3), the Examiner has found claims 1, 4, 6-8, 10, 12-13, 17, 20, 27-28, and 63 to be rendered obvious by Streeter.

As noted above, independent claims 1 and 63, directed to a implantable device for repairing a cardiac valve, have been amended to now recite *each restraining member being sufficiently situated from an adjacent member, so as to support free margins of any leaflets and to minimize* an occurrence of the leaflets from slipping through a space between adjacent restraining members. Support for this amendment can be found, for example, in paragraphs 55 and 56 of the present application.

In contrast, Streeter lacks any teaching or disclosure directed to minimizing leaflet contact in a manner so as to support the free margin of the leaflets. As previously stated, Streeter is directed to a valve shield that includes a shaped sheet of material adapted to be affixed to the annulus of a valve and adapted to extend over at least a portion of a valve leaflet, so as to assist or replace the closing function of that valve leaflet. However, nowhere within Streeter is there any suggestion, teaching or disclosure directed to the restraining members being sufficiently spaced from one restraining member in order to minimize slippage or protrusion of the leaflet through the space between adjacent restraining members.

Moreover, contrary to the assertion by the Examiner that the Streeter invention is so similar to the present invention that it renders the present invention obvious, it should be appreciated that the spacing of the restraining members in the Streeter device may not be sufficient to minimize leaflet protrusion. If the Examiner may note, in paragraph 56 of the present application provides that the free margin of a leaflet must be supported at least every 5-7 millimeters along the leaflet. Any spacing between adjacent restraining members larger than 5-7 millimeters would, thus, likely result in protrusion of the leaflets through such a spacing. Furthermore, since the Streeter device and the device of the present invention must be relatively similar in size to cover

the leaflet valve, and since the Streeter invention contains only five restraining members, while the present invention contains six restraining members, the use of only five restraining members across a similarly sized device would result in a space larger than 5-7 millimeters between adjacent members. A spacing larger than 5-7 millimeters would not be sufficient to minimize protrusion of the leaflet through such a space.

Since Streeter fails to teach certain features of claims 1 and 63, Applicants submit that one skilled in the art, reading Streeter, would not find it obvious to modify Streeter in a manner suggested by the Examiner to obtain the invention set forth in claims 1 and 63, that is, to provided sufficiently situate adjacent restraining members from one another so as to minimize an occurrence of the leaflets from slipping through a space between adjacent restraining members.

Claims 4, 6-8, 10, 12-13, 17, 20, and 27-28 are dependent from claim 1. As a result, they must be read to include the limitations set forth in their respective base claim. In particular, each of the dependent claims must be read to include the limitation of situating the restraining members from one another in such a manner so as to minimize an occurrence of the leaflets from slipping through a space between adjacent restraining members.

As noted above, Streeter fails to teach such a feature or capability.

Accordingly, Applicant submits that a person skilled in the art reading Streeter would not find it obvious to modify Streeter in the manner suggested by the Examiner to obtain the invention set forth in claims 4, 6-8, 10, 12-13, 17, 20, and 27-28 . These claims, as a result, cannot be rendered obvious by Streeter.

Conclusion

In view of the foregoing remarks, Applicants submit that the pending claims are neither anticipated nor rendered obvious by Streeter.

Accordingly, Applicants submit that the claims are in condition for allowance. Withdrawal of the pending rejections, and early and favorable reconsideration are respectfully solicited. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned at (617) 310-6000.

Applicants do not believe that any additional extension or additional fee is required in connection with this Response. However, should any extension or fee be required for timely consideration of the present application, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this application be charged to Deposit Account No. 50-02678, Reference 113002-010101.

Respectfully submitted,

/Chinh H. Pham/
Chinh H. Pham, Reg. No. 39,329

GREENBERG TRAURIG, LLP
One International Place
Boston, MA 02110
Tel: 617/310-6000
Fax: 617/310-6001